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09/938,667	08/27/2001	Jens Petersen	60117.000006	2505

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/938,667	PETERSEN, JENS	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-17,29-32,34-38,52,53,62,67-69,78-80 and 82-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-17,29-32,34-38,52,53,62,67-69,78-80 and 82-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination, amendment, remarks, filed 10/08/2007. Claims 9 and 85 are amended. Claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 78-80 and 82-90 are pending.

Previous rejections that are not reiterated herein are withdrawn.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/08/07 has been entered.

The Claims :

Claim 9 is drawn to method of treating urinary incontinence, the method "comprises increasing resistance of passage through a urethra comprising administering prosthetic device that comprises "hydrogel, comprising about 0.5 to 25% by weight based on the total weight of the hydrogel, of a polymer prepared by a method comprising combining acrylamide and methylene bis-acrylamide: wherein the hydrogel includes less than 50 ppm monomeric units, has a complex viscosities of about 2-50 Pas and has an elastic modulus of about 1-200 Pa."

"Prepared by a method ... bis-acrylamide," is the process of preparing the acrylamide hydrogel. "Less than 50 ppm monomeric units" in the hydrogel represent residual amounts of the starting acrylamide monomer and the cross-linker methylene bis-acrylamide. The viscosity and the elastic modulus are inherent properties of the hydrogel.

Claim 78 is similar to claim 9 except that specific mode of administration of the acrylamide hydrogel is recited in claim 78, which is injected into the urethra.

Claim 79 is similar to claims 9 and 78.

Claim 80 is similar to claim 9 except that the urethra is bulked by administering prosthetic device.

New claim 85 is similar to claim 9 except that administration of prosthetic device provides adequate resistance in a urethra. "Adequate resistance" is relative and given to artisan's judgment of what is adequate.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention. 85,

3. Claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 82-84 and 86-90 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

Claim 9 now says "resistance of passage of urine through the urethra" and applicant has

not pointed to the section of the specification as originally filed that supports this amendment. The specification as originally filed does not provide support for that limitation.

Applicant may direct the examiner to the section of the original specification that provides the support or provide an explanation as to why the limitation is supported by the originally filed specification.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 78-80 and 82-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pavlyk (US 5,798,096) in view of RU 2148957 and applicants admission (interview of 2/23/06 and remarks filed 2/27/06) and further in view of Annis et al. (US 4,857,041).

Generic claims 9 and 78-80 are analyzed above as described under "**The Claims**:" It is noted in the analysis for claim 9 that the method of treating urinary incontinence comprises administering to the urethra. Claim 79 injects the hydrogel into urethra. Claims 78 and 80 administer the endoprosthesis and increasing the resistance of the urethra and bulking are intended uses of the hydrogel. The other aspects of the properties of the hydrogel as described for claim 9 is the same for the claims 78-80.

Pavlyk discloses cross-linked polyacrylamide hydrogel (claims 52 and 53) produced from acrylamide and methylene bis-acrylamide monomers and apyrogenic or pyrogen free water (abstract; Table 1) meeting the limitations of the acrylamide hydrogels and pyrogen free water of the claims; the hydrogel is used as endoprosthesis by way of sterile injections into tissues by way of canals of the corporum cavernosum (column 1, lines 5-10; column 10, lines 37-56). Pavlyk discloses that the hydrogel provides bulking (column 3, lines 17-18); the hydrogel of Pavlyk has low viscosity (column 2, lines 58-67) and the Pavlyk hydrogel would inherently have the viscosity properties recited. The amount of the acrylamide in the hydrogel ranges from 3.5 to 9.0% touching pints along the claimed acrylamide range of 0.5 to 25% as in the generic claims 9 and 78-80. The hydrogel of Pavlyk would inherently exhibit the intended use of the claimed hydrogel and would have the claimed properties since a product and its properties cannot be separated and thus meets claims 13, 35, 36, 67-69. The 3.5% acrylamide of Pavlyk is less than 15%, 10%, 7.5%, 5% (claims 11, 29-31) and 3.5% is at least 1%, 1.6% (claims 12, 34). The amount of water or aqueous solution in Pavlyk ranges from 88% to 96% (see Table 1) meeting the water limitation of claims 14, 62 and Pavlyk's use of pyrogen free water meets claims 63. Since the reaction between the acrylamide monomer and the methylene bis-acrylamide monomer cross-linking agent goes to completion, since the Pavlyk reference does not disclose the presence of residual monomeric units in the acrylamide hydrogel, and since the residual monomer in the product is expected to be very minimal if any, Pavlyk renders less than 50 ppm monomeric unit obvious.

While Pavlyk discloses injecting the hydrogel into caverns that may meet canals or conduits or channels, and if the cavern does not specifically read on channels or tubes, it is

known according to the RU reference 2,148,957 and as admitted by applicant that the polyacrylamide hydrogel, "a gel within the scope disclosed by Pavlyk" is injected into the ostium of the ureter to impede the flow of urine (see paragraph of remarks filed 2/27/06 and first full paragraph on page 10 of remarks filed 10/08/07), with injecting meeting claims 78 and 79. Furthermore, it is known in the art that urinary incontinence is treated by administering prosthetic device comprising polyacrylamide hydrogel into the urethra (Annis at abstract; column 2, lines 65-68; column 3, lines 12-23). Therefore, it would have been obvious to one of ordinary skill in the art to inject hydrogel into the caverns that would inherently act as a bulking agent or increasing the resistance of passage of urine through the caverns. One having ordinary skill in the art would have been motivated to inject the acrylamide hydrogel into the ostium of the ureter or into the urethra with the expectation that the hydrogel would act as a bulking material that would create increased resistance to the flow urine in the urethra or the ureter that would lead to the treatment of urinary incontinence.

Response to Arguments

6. Applicant's arguments filed 10/08/07 have been fully considered but they are not persuasive.

Applicant argues that a) the prosthetic device performs no physiological/biological function an that there is no teaching in Pavlyk to using the polyacrylamide gel to treat urinary incontinence, that Pavlyk clearly teaches polymer concentrations below 3.5% make the hydrogel unstable while concentrations above 6.0% decrease fluidity of the hydrogel; b) the RU reference (Sknar) does not also treat urinary incontinence but vesicouretal reflux ("VUR") and also that the RU reference uses the hydrogel to impede

the normal passive flow of urine from the kidney through the ureter and then to the bladder; c) the Annis prosthetic is rigid and does not include a viscous, injectable polyacrylamide hydrogel as in the invention and that Annis does not administer the solid prosthesis into the urethra and does not teach bulking of the urethra with the prosthetic device, d) the examiner has not provided technical basis for coming to the conclusion that the Pavlyk hydrogel would be suitable for use as a urethral bulking device or that the reaction of the acrylamide and the methylene bis-acrylamide in Pavlyk would have gone to completion and that there is no express statement in Pavlyk that the reaction proceeded to completion,

Response:

Regarding a), examiner agrees with applicant that Pavlyk does not say that the acrylamide is used to treat urinary incontinence and that is why the rejection is made in combination with other references, such as applicant's admitted prior art and Annis, that render the claimed process obvious. While applicant states that Pavlyk uses between 3.5% and 6.0% of acrylamide, it is noted that 3.5-6.0% lies within the recited range of 0.5% to 25% and 6% or 3.5% is less than 15% (claim 11), 10% (claim 29), 7.5% (claims 39) or 5% (claims 3) with the 6% or 3.5% being at least 1% and 1.6% (claims 12 and 34). Physiological or biological function is a property of the polymer or acrylamide within the hydrogel and since the claimed invention uses acrylamide gel and the prior art uses acrylamide gel, it flows that the function of the hydrogel that is attributable to the acrylamide would also be present in the hydrogel of the prior art that comprises acrylamide. Therefore, the prosthesis of Pavlyk comprising acrylamide hydrogel would also inherently perform physiological/biological function.

Regarding b), it is noted that if the acrylamide of the RU reference, which as per applicant is the same scope as that administered by Pavlyk, impedes the flow of urine, then the acrylamide of Pavlyk would also impede urine flow when administered to portions of the urinary tract. Furthermore, the RU reference (Sknar) is relied upon for teaching that the polyacrylamide hydrogel, which is of the scope of Pavlyk, is known and used for injection into the ostium of the ureter to impede the flow of urine as described in the rejection. Thus, the RU reference (Sknar) is not relied upon for treating "VUR" or urinary incontinence.

With regards to Annis and c), Annis was relied upon for disclosing that prosthetic device comprising acrylamide is administered to the urethra to treat urinary incontinence such that it would be obvious to use the device of Pavlyk to treat urinary incontinence.

Regarding applicant's argument that the present invention is directed to the treatment of urinary incontinence by bulking the urethra, it is noted that the method step of claim 9 does not bulk the urethra, claims 15 and 78 talk about injecting the hydrogel, claim 79 talks about injecting "urethral bulking agent" where the urethral bulking agent is a hydrogel and Pavlyk teaches hydrogel, while for claim 80 the bulking of the urethra is done by administration and the administration reads on the administration of hydrogel by the prior art. Therefore, the combined references render the claimed invention obvious.

Regarding d), applicant has not provided factual evidence that the reaction between the acrylamide and the methylene bis-acrylamide does not go completion, the examiner has not used any conclusion except to note that a product, that is the acrylamide hydrogel, used in the method of the instant invention is produced by reaction between acrylamide and methylene bis-acrylamide, in the same manner, Pavlyk forms the acrylamide hydrogel by reacting methylene

bis-acrylamide and acrylamide. Same product is formed from the reactions and the USPTO is not equipped with laboratory to determine which of the method, the method of the prior art or the claimed method of preparing acrylamide hydrogel, goes to completion. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). There is no erroneous conclusion when the RU reference (Sknar) provided by applicant teaches that the polyacrylamide hydrogel of the scope of the hydrogel of Pavlyk is known and used for injection into the ostium of the ureter to impede urine flow.

The claimed method administers (see claim 9) acrylamide hydrogel to treat incontinence. In the same manner, the combined teaching of the prior art administers acrylamide hydrogel to treat incontinence (see Annis and Pavlyk). The Annis art specifically teaches that acrylamide hydrogels is administered to treat incontinence. There does not appear to be any difference between the acrylamide hydrogel claimed to be used to treat urinary incontinence and the acrylamide hydrogel of the prior art.

7. Claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 78-80 and 82-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vogel et al. (US 6,335,028) in view of RU 2148957 and applicants admission (interview of 2/23/06 and remarks filed 2/27/06) and further in view of Annis et al. (US 4,857,041).

Vogel discloses method of treating urinary incontinence by administering, by injection into esophageal wall or via the urethra and into the wall of the bladder sphincter and urethral wall, acrylamide based hydrogel produced with about 25 to about 98% methacrylamide and about 2-about 50% methylene bis-acrylamide and containing autologous cells (abstract; column 4, lines 31, 32, 51-67; column 6, lines 1-16; column 10, lines 40-44; Examples 1 and 2); sterile and pyrogen free injectable solutions are employed for the storage of the hydrogel product (column 6, lines 58-60). Since the Vogel reference does not disclose the presence of residual monomeric units in the acrylamide hydrogel, and since the residual monomer in the product is expected to be very minimal if any, Vogel renders less than 50 ppm monomeric unit obvious.

Vogel discloses injectable acrylamide based hydrogel, and being injectable, it would have inherent viscosity that is characteristic of injectable hydrogels such as the claimed viscosities. The hydrogel contains cells (column 4, line 57) or other active agents (column 10, lines 54-67). The viscosity and modulus of elasticity are properties of the hydrogel. The amount of the polyacrylamide would approximate the amount recited since the starting amount of the acrylamide is at about 25% and the expected amount of the end product would be less than the starting 25%. Vogel does not state that the hydrogel is prosthesis. But it is known that acrylamide based hydrogels are used as endoprosthesis for administration into the ostium of the ureter for impeding the flow of urine according to RU 2148957 and applicant's admission (interview of 2/23/06 and remarks filed 2/27/06 and page 10 of remarks filed 10/08/07) and further that Annis discloses treating urinary incontinence by administering prosthetic device comprising polyacrylamide hydrogel into the urethra (abstract; column 2, lines 65-68; column 3, lines 12-23). Therefore, it would have been obvious to one of ordinary skill in the art at the time

the invention was made to inject the cross-linked polyacrylamide based hydrogel of Vogel through the urethra to treat urinary incontinence. One having ordinary skill in the art would have been motivated to administer the hydrogel of Vogel as a prosthetic device according to the teachings of Annis, the RU reference or applicant's admitted prior art with the expectation bulking the urethra to treat urinary incontinence or impeding urine flow.

Response to Arguments

8. Applicant's arguments filed 10/08/07 have been fully considered but they are not persuasive.

Applicant argues that a) Vogel teaches suspension of microparticles and as such would not have the properties/complex viscosity of the polyacrylamide hydrogel of the claimed invention, b) that one would not be motivated to use the hydrogel of the RU reference (Sknar) or Annis in the Vogel method because of the difference in passive function of the ureter and active function of urethra, c) the Annis prosthesis is not placed into the urethra but placed outside of the urethra, d) the polymer of Vogel would not inherently have the complex viscosity of the claimed hydrogel.

Response:

Regarding a), complex viscosity is an inherent property of the hydrogel, and in this case the acrylamide hydrogel so that the hydrogel of Vogel would inherently have complex viscosity and applicant has not factually shown that the acrylamide composition of Vogel would not have complex viscosity. Specifically, Vogel contemplates injecting the hydrogel composition (see claims 8 and 9). Regarding b), the RU reference is relied upon for a teaching that acrylamide impedes the flow of urine in the urinary tract as admitted by applicant and as stated by applicant

in the remarks filed 5/24/07. Furthermore, Annis teaches administering prosthesis comprising acrylamide into the urethra to treat urinary incontinence. Regarding c), it is noted that claim 9 at least administers a prosthetic device, where administration is not specific to placing the hydrogel in the urethra in the method step of the claim. The examiner has not made erroneous suggestion regarding the Vogel reference because Vogel envisions treating urinary incontinence with acrylamide type hydrogel as described above. Regarding d), applicant has not provided factual evidence that the hydrogel of Vogel would not have complex viscosity even though applicant says that the product used by Vogel is a suspension, which suspension is injectable. It is known in the art that administering acrylamide to the urethra treats urinary incontinence (Annis at abstract; column 2, lines 65-68; column 3, lines 12-23) so that the skilled artisan, taking the references together would be motivated to use the hydrogel of Vogel to treat incontinence using a suspension that is injectable for injection into the urethra, even if outside of the urethra. The claims at least in 9 and the claims dependent on 9 do not inject the hydrogel into the urethra.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 78-80 and 82-90 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10-14, 16-18, 20-42 of copending Application No. 11/469,213 (US 20070020226). Although the conflicting claims are not identical, they are not patentably distinct from each other because co-pending claims 1, 18, 36 treat incontinence with polyacrylamide hydrogel where the incontinence is urinary incontinence. The claims dependent on 36 further describe the hydrogel.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Suggestion:

It was suggested to applicant, as was suggested previously and as stated on page 8 of applicant's remarks of 10/20/06, that the hydrogel be injected into urethra at 0.5 cm distally from the neck of the bladder to overcome the art, explanation of why that position provides unusual and unexpected result may be necessary. Please note that Vogel injects hydrogel of the type claimed into the urethra. It is noted that applicant has not commented on the above suggestion.

Applicant's request for Interview:

Because the issues remaining to be resolved are many, the examiner has not called the applicant as requested. However, the applicant may call the examiner to schedule an interview

if the applicant deems that an interview with the examiner may facilitate the prosecution of the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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